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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,657	06/29/2001	Debra A. Timm	JOHNA.061A	9725

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

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DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,657

Applicant(s)

TIMM ET AL.

Examiner

Jennifer Kolb Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The rejection of claims 1, 16, and those depending therefrom has been withdrawn based on Applicant's amendment.

Claim Rejections - 35 USC § 103

2. Claims 1-5, 8, 11, 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikada et al. (U.S. Pat. 4,743,258).

Examiner maintains the rejection of claims 1-5, 8, 11, 13-18.

Claims 19 and 20 have been added to this rejection because Ikada's inherent sterilization would not impact the activity of the coating material because the peroxides used are critical to the production of said coating.

3. Claims 1-5, 8, 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akagi et al. (U.S. Pat. 4,728,564).

Examiner maintains the rejection of claims 1-5, 8, 16-18.

Claims 19 and 20 have been added to this rejection because Akagi's inherent sterilization would not impact the activity of the coating material because the peroxides used are critical to the production of said coating.

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4. Claims 1, 3, 5-15, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendriks (U.S. Pat. 5866113) in view of Spencer (U.S. Pat. 5,656,238).

Examiner maintains the rejection of claims 1, 3, and 5-15.

Claim 19 has been added to this rejection because the sterilization method of Hendriks in view of Spencer would not be used if it "severely" impacted the activity of the coating material desired on the medical device.

Response to Arguments

5. Applicant's arguments filed 7/8/2002 have been fully considered but they are not persuasive.

Applicant argues that Ikada does not teach sterilization by any means and that an ordinary artisan would not assume that all peroxides would produce sterilization.

Examiner agrees that sterilization is not specifically taught. However, it is Examiner's position that sterilization by Ikada is inherent in the method of Ikada for those reasons outlined in the previous office action. Particularly, Ikada merely teaches the use of peroxides in a plasma discharge method of graft polymerizing monomers to the surface. One of ordinary skill in the art desiring to produce peroxides in the plasma of Ikada would have used his knowledge of the art or looked to the prior art for common, affordable, readily available sources of peroxides. Ahlfors was cited in the previous office action for teaching hydrogen peroxide as a common chemical species belonging to the class of chemicals containing an oxygen-oxygen bond known as peroxides.

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Additionally, Spencer was cited in the previous office action for teaching the use of hydrogen peroxide in a plasma. In a plasma, hydrogen peroxide is said to dissociate into its reactive species. These reactive species are "peroxide radicals", as required by Ikada's plasma. Spencer and Ahlfors are noted here to show that one of ordinary skill in the art looking for a source of peroxides for use in the plasma discharge operation of Ikada would have looked to the prior art and found hydrogen peroxide to be such a source. Hydrogen peroxide is a safe, common, affordable, and readily available source of peroxides that is known in the art to be compatible in plasmas with medical devices, as shown by Spencer. Because Ikada fails to specify any criticality of selecting a specific source of peroxides for use in his plasma treatment, it would have been incumbent upon one of ordinary skill in the art to look to the prior art for suitable sources, as selection of a source would be required to perform the method of Ikada. Upon selecting hydrogen peroxide as the source, sterilization would have been inherent. The ordinary artisan would not "assume" all peroxides produce sterilization. Examiner merely argues that it would have been obvious to one of ordinary skill in the art to select hydrogen peroxide as the peroxide source in the plasma reaction of Ikada, at which point, sterilization would have become inherent.

Applicant cites the '876 patent which states that concentrations of hydrogen peroxide below a certain limit "were not adequate to provide complete sterilization under the conditions of the '876 patent". Applicant argues that since there is no teaching in Ikada of the concentration of peroxide, that sterilization is not inherent.

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Examiner notes that while sterilization is not "complete" below a certain concentration of hydrogen peroxide, that some degree of sterilization still occurs. Also, this concentration limit was for "the conditions of the '876 patent". This implies that under different conditions, different concentrations are needed for sterilization. Since neither Applicant nor Ikada is working under the conditions of the '876 patent, it can not be assumed that the concentration level required by the '876 patent is relevant. Furthermore, Examiner notes that Applicant does not claim any concentration requirement.

Applicant argues that the examples of Ikada teach a plasma treatment time that is too short to allow for sterilization.

Examiner notes that Applicant does not claim a time for sterilization, nor has Applicant provided any proof that such a timeframe is insufficient for *any* level of sterilization to occur.

Applicant argues that the order of the plasma steps is important. If peroxide is introduced while the plasma is generated, sporicidal activity is observed with lower power, but sporicidal activity is "poor" at higher powers. Applicant argues, then, that even if sterilization occurs, that there is no guarantee that it is maintained through subsequent process steps. Lastly, then, Applicant notes that sterilization is always the last step of his method.

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Examiner has considered this argument, however, she notes that Applicant teaches that sporicidal activity is present with low power, but "poor" at high power. Therefore, it appears that *some* sporicidal activity or sterilization will occur at any level. Additionally, in regards to the maintenance of sterilization, Applicant has not claimed that sterilization lasts any specified amount of time. In fact, it is Examiner's position that sterilization must be lost at some point subsequent to the sterilizing step.

Regarding Applicant's arguments concerning the Akagi reference that are similar to those made regarding the Ikada reference, Examiner refers to those statements made, above.

Applicant argues that Akagi teaches the use of oxygen to form the low temperature plasma, not hydrogen peroxide.

Examiner notes that Akagi's "Process C" occurs in the presence of oxygen, however the process is one of converting plasma radicals to peroxides in the presence of oxygen.

Oxygen is not present in the process to the exclusion of other chemicals and Examiner notes that Akagi requires a peroxide source in the same manner as required by Ikada, outlined above.

Regarding the Hendriks and Spencer rejection, Applicant argues that there is no motivation in the references to combine the references. Thus, Applicant argues that it

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would not have been obvious to use the hydrogen peroxide sterilization step of Spencer in the method of Hendriks.

Examiner disagrees. Hendriks graft polymerizes polymers onto medical devices and sterilizes such devices using ethylene oxide. Spencer teaches an alternative method of sterilizing medical devices using a plasma of hydrogen peroxide. Spencer teaches that his "sterilization system can safely process medical items currently sterilized by ethylene oxide" (col. 1, lines 42-44). Therefore it would have been obvious to one of ordinary skill in the art to use the hydrogen peroxide sterilization method of Spencer in lieu of or interchangeably with the ethylene oxide sterilization step of Hendriks with the expectation of a "safe" method on medical items, as taught by Spencer.

Applicant argues that his own specification teaches against combining just any graft-polymerizing step (such as Hendriks) with just any sterilization step (such as that of Spencer) because the results of any given combination are not predictable.

Examiner notes that one of ordinary skill in the art would be unaware of Applicant's teachings when combining the prior art of Hendriks and Spencer. Furthermore, as is taught by Spencer, the combination of his sterilization method is predictably safe and effective for medical devices previously sterilized with the alternative method of ethylene oxide. Therefore there would in fact be a reasonably predictable expectation of success when combining these references.

Applicant argues that Examiner uses hindsight in combining Spencer and Hendriks.

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Examiner disagrees. Examiner used the teachings of Spencer to combine said references as outlined above, not hindsight. Additionally, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
October 18, 2002



SHRIVE P. BECK
SUPERVISORY PATENT EXAMINER
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